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No. 10-770

IN THE

Supreme Court of the United States

MYLAN INC., MYLAN LABORATORIES INC., MYLAN PHARMACEUTICALS INC. AND MATRIX LABORATORIES LTD.,

Petitioners,

v.

DAIICHI SANKYO COMPANY, LTD. AND DAIICHI SANKYO, INC.,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

REPLY BRIEF FOR PETITIONERS

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I. Federal Circuit Precedent Evidences the Circuit's Unique (and Improper) Treatment of New Chemical Compound Cases.

Daiichi Sankyo asserts that Mylan selectively excluded cases to arrive at a pattern of nonobviousness in post-*KSR* new chemical compound cases. (Opp'n Br. at 18.) However, the excluded cases cited in the opposition brief did not use the lead compound test because *they were not new chemical compound cases.* (Opp'n Br. at 18 & n.14 (noting exclusion of cases involving "non-pharmaceutical chemical compounds, salts, formulations, and methods of treatment").) Although not directly relevant to the lead compound test, they actually *support* Mylan's argument for an alternative to the lead compound test that emphasizes an "obvious to try" perspective in medicinal chemistry cases. *See, e.g., Bayer Schering Pharma AG v. Barr Labs., Inc.*, 575 F.3d 1341, 1350 (Fed. Cir. 2009) (formulation claim held obvious under an obvious to try rationale); *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1364 (Fed. Cir. 2007) (same). That the Federal Circuit permits flexibility in cases not involving new chemical compounds underscores Mylan's point—imposition of an *exclusive test* for new chemical compounds distorts the flexible obviousness analysis required by *KSR*.

Daiichi Sankyo's criticism of Mylan for excluding *Altana* and *Novartis* is also misplaced. (Opp'n Br. at 18 & n.13.) Mylan specifically addressed the procedural posture and consequent irrelevance of such cases. (*See* Pet. at 12 n.6.) Cases using the lead compound test on a motion for preliminary injunction

are not pertinent for this purpose because the relevant standard of proof in such cases is much *lower* than the high standard the lead compound test sets on the merits. *Altana Pharma AG v. Teva Pharm. USA, Inc.*, 566 F.3d 999, 1005-06 (Fed. Cir. 2009) (explaining that movant's standard for a preliminary injunction is "reasonable likelihood of success on the merits," which is precluded by non-movant's raising of a "substantial question of invalidity"). *Novartis Pharmaceuticals Corp. v. Teva Pharmaceuticals USA, Inc.*, is inapposite for the same reason. 280 Fed. Appx. 996 (Fed. Cir. 2008) (affirming, in a nonprecedential decision without opinion, an unpublished district court grant of a preliminary injunction).

Additionally, Daiichi Sankyo argues that in discussing seven rationales to be applied in obviousness determinations generally, the PTO Guidelines do not suggest a specific standard should be exclusively applied to chemical compound cases. (Opp'n Br. at 21 n.15.) This argument flatly ignores the PTO's statement that:

> In the chemical arts, the cases involving the so-called "lead compounds" form an important subgroup of the obviousness cases that are based on substitution. The Federal Circuit has had a number of opportunities since the *KSR* decision to discuss the circumstances under which it would have been obvious to modify a known compound to arrive at a claimed compound. *The following cases* [*Eisai, P&G, Altana*] *explore the selection of a lead compound, the need to provide a*

> *reason for any proposed modification, and the predictability of the result.*

2010 PTO Guidelines at 53,651 (emphasis added).[1]

In short, the opposition brief does not rebut Mylan's point that this Court should grant certiorari to consider whether application of the lead compound test to new chemical compounds precludes a flexible analysis of the particular facts of each case. Daiichi Sankyo's attempt to find exceptions to a "cherry-picked" pattern only reinforces Mylan's point.[2]

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[1] The PTO's reliance on the Federal Circuit's lead compound test revives the problems it faced with the "suggestion" test pre-*KSR*. *See, e.g., In re Public Hearing on Competition and Intellectual Property Law and Policy in The Knowledge-Based Economy Before the Federal Trade Commission*, Transcript at 137 (July 10, 2002) (statement of Stephen G. Kunin, Deputy Commissioner for Patent Examination Policy) ("[N]ot only must there be a suggestion, it seems like there must be an express motivation. It's almost that if you don't have the glue expressly leading you all the way, there isn't any basis to establish something would have been obvious."), *available at* http://www.ftc.gov/opp/intellect/020710trans.pdf.

[2] The opposition brief inaccurately attempts to portray Mylan's petition as merely an effort to have this Court second-guess the district court's factual findings. Obviousness "lends itself to several basic factual inquiries," but patent validity is ultimately a question of law. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). And, the limited standard of review attendant to fact finding is irrelevant where, as here, the fact finding was in an erroneous legal context. *See Pullman-Standard, Div. of Pullman v. Swint*, 456 U.S. 273, 287 (1982). If this Court ultimately holds that the Federal Circuit's lead compound test is inconsistent with *KSR*, then a remand is required for application of the appropriate legal standard to the evidence.

II. An Alternative Analysis That Focuses on "Obviousness to Try" Does Not Suffer From Hindsight Bias.

Daiichi Sankyo characterizes Mylan's proposed alternative approach to the lead compound test as "rel[ying] entirely upon hindsight." (Opp'n Br. at 4, 16.) This characterization is unfounded.

Mylan challenges the lead compound test because of its rigidity and proposes that in new chemical compound cases, the obviousness analysis should focus less on "predictability" *per se* and more on whether the alleged invention was "obvious to try." (Pet. at 26.) Approaching the analysis from an "obvious to try" perspective no more relies on hindsight than does approaching the analysis from a "predictability" perspective: both perspectives require reference to the claimed compound, but both are viewed by one of ordinary skill in the art *at the time of the alleged invention*. Both perspectives must guard against hindsight bias, but neither is analytically more susceptible to it.

As the Solicitor General's invitation brief in *KSR* noted, the ability of courts and patent examiners to avoid hindsight bias in applying a flexible obviousness analysis should not be underestimated:

> The Federal Circuit's [TSM] test effectively constricts this Court's guidance in *Graham* respecting the nonobviousness inquiry, it fails to account adequately for the problem-solving abilities of persons of ordinary skill in the art, and it underestimates the capabilities of courts and patent

> examiners to "resist the temptation" of hindsight and to consider fairly the question of obviousness. Moreover, if there is a need for the Federal Circuit's strict measures to guard against the possibility of hindsight, this Court should make that decision itself.

United States *Amicus Curiae* Invitation Br. at 16, *KSR Int'l Co. v. Teleflex Inc.*, No. 04-1350 (2007) (supporting a grant of certiorari) (internal citation omitted).[3]

The Federal Circuit's imposition of the lead compound test revives the same concerns raised by the Solicitor General in *KSR* that the TSM test "renders patent examination and litigation more costly, it grants patent applicants unjustified rewards for disclosing non-innovating subject matter, and it forecloses competitors from using the public

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[3] The Solicitor General's position in *KSR* is not only directly applicable to this case but is of additional relevance in view of policies articulated by Congress in passing the Hatch-Waxman Act, and echoed recently by the Executive Branch, in favor of accelerating the entry of generic drugs into the marketplace to reduce healthcare costs. *See, e.g.*, OFFICE OF MANAGEMENT AND BUDGET, FISCAL YEAR 2012 BUDGET OF THE U.S. GOVERNMENT 81 (2011) ("The high cost of prescription drugs is a burden for many Americans. The Administration will accelerate access to more affordable pharmaceuticals that will lead to cost savings for consumers and health programs across the Federal Government."), *available at* http://www.whitehouse.gov/sites/default/files/omb/budget/fy2012/assets/budget.pdf; Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

storehouse of knowledge that should be freely available to all." *Id.* This "substantial obstacle" prompted the Solicitor General to urge this Court's grant of certiorari because:

> This Court's decisions nowhere suggest that a court *must* make the *specific findings* that the Federal Circuit requires. To the contrary, this Court has found that a claimed invention would have been obvious based on the small difference between the prior art and what the inventor claimed, without any mention of [TSM].

Id. at 13 n.5 (emphasis in original); *see also* United States *Amicus Curiae* Merits Br. at 16-19, *KSR Int'l Co. v. Teleflex Inc.*, No. 04-1350 (2007) (explaining the fallacy of insisting on "specific" and "particular" showings where such information is often absent from "rapidly expanding technological fields that create sudden economic incentives to adopt or apply existing knowledge in new but readily conceivable combinations").

Indeed, this Court made clear in *KSR* that an obvious to try perspective is (1) valid ("the fact that a combination was obvious to try might show that it was obvious under § 103"), (2) need not suffer from hindsight bias ("[a] factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning"), and (3) as a common sense alternative to a rigid approach, is preferred ("[r]igid preventative rules that deny factfinders recourse to common sense, however, are neither necessary under our case law nor consistent with it"). 550 U.S. 398, 421 (2007). In

light of this Court's reasoning in *KSR*, it is illogical for Daiichi Sankyo now to assert that an obviousness analysis that focuses on "obviousness to try" in favor of "predictability" necessarily suffers from hindsight bias.

III. Mylan Preserved the Question Presented in the Petition.

Daiichi Sankyo argues that Mylan cannot question the application of the lead compound test to new chemical compounds because (1) Mylan chose to base its defense in this case on the lead compound test and (2) Mylan's arguments challenging the test "were not made below." (Opp'n Br. at 29.) This argument fails on both points.

First, the Federal Circuit applies the lead compound test as the exclusive standard "in cases involving new chemical compounds." *Takeda Chem. Indus. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1357 (Fed. Cir. 2007); *see also, e.g.*, *Eisai Co. v. Dr. Reddy's Labs. Ltd.*, 533 F.3d 1353, 1359 (Fed. Cir. 2008) ("[P]ost-*KSR*, a prima facie case of obviousness for a chemical compound still, in general, begins with the reasoned identification of a lead compound."). Therefore, Mylan was not in a position to defend the action on a different basis and ask the district court to depart from the controlling Federal Circuit precedent. In its appeal to the Federal Circuit, Mylan repeatedly advocated for a more flexible obviousness analysis and against a restricted view of the lead compound test. (*See, e.g.*, Appellant Br. at 2 (describing the district court's "rigid application of the obviousness standard" as contrary to *KSR*); Appellant Reply Br. at 1 (stating "[o]bviousness of chemical compounds does not rely on a '"rigid and

mandatory formula'" and noting the "fundamental inconsistency between the district court's overly formulaic analysis and the flexible approach to determining obviousness required by *KSR*").)

Mylan also specifically cited the Federal Circuit's precedent to advocate flexibility over an acute focus on predictability. (*See, e.g.*, Appellant Br. at 42 (noting that "by disregarding known pharmaceutical practice in determining the choices that a skilled artisan would make," the district court made the same error the Federal Circuit warned against in *Pfizer v. Apotex*, 480 F.3d 1348 (Fed. Cir. 2007)); *id.* at 45 (quoting Federal Circuit cases stating "obviousness cannot be avoided simply by a showing of some degree of unpredictability in the art so long as there was a reasonable probability of success."); Appellant Reply Br. at 1 ("Obviousness of chemical compounds does not rely on a 'rigid and mandatory' formula"); *id.* at 29 (noting, in response to Daiichi Sankyo's argument that the ARB field is unpredictable, that Federal Circuit cases find that unpredictability does not guarantee conclusions of nonobviousness or patentability).

Second, this Court has long held that legal questions grounded in a properly raised claim below are appropriate for review, regardless of how the argument was previously characterized. *See MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 125 (2007) ("That petitioner limited its contract argument to a few pages of its appellate brief does not suggest a waiver; it merely reflects counsel's sound assessment that the argument would be futile" where Federal Circuit precedent precluded jurisdiction over petitioner's contract claims); *PGA*

Tour, Inc. v. Martin, 532 U.S. 661, 678 n.27 (2001) (responding to the argument that "petitioner's failure to make this exact argument below precludes its assertion here" by noting that the scope of the statute in question was raised in the lower courts and "[g]iven the importance of the issue, we exercise our discretion to consider it"); *Harris Trust and Sav. Bank v. Salomon Smith Barney Inc.*, 530 U.S. 238, 245-46 & n.2 (2000) (recognizing that even where petitioners did not explicitly articulate their theory, the "Seventh Circuit understood the tenor of the argument" and stating "[o]nce a federal claim is properly presented, a party can make any argument in support of that claim; parties are not limited to the precise arguments they made below") (quoting *Yee v. City of Escondido*, 503 U.S. 519, 535 (1992) (holding that petitioners that properly raised a federal claim in the prior proceedings "could have formulated any argument they liked in support of that claim here")).

Accordingly, Mylan preserved the question presented in the petition. This case is an appropriate vehicle for resolving that question for all the reasons previously stated. (Pet. at 29-31.)

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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